

REMARKS

This communication responds to the Office Action of May 1, 2008, in which claims 1, 3-6, 8, 10, 12, 13, 15, 17-34 and 36 were rejected. (Claims 2, 7, 9, 11, 14, 16 and 35 were previously canceled.) In response, new figures 1a and 1b have been added. A replacement sheet including Figs. 1, 1a and 1b is submitted herewith. The specification has been amended to include a description of figures 1a and 1b. Claims 1, 3-6, 8, 12, 13, 15, 17-18, 22, 26, 27, and 36 have amended, and claims 33 and 34 have been canceled. No new matter has been added by these modifications.

Reconsideration and allowance of the pending claims are requested.

Examiner Interview

The Examiner interview that was conducted on Wednesday, July 2, 2008 between Examiner Desanto and Bridget Hayden is appreciated. During the interview, the independent claim limitations of compressible and hollow spaces were discussed. While no agreement was reached, it is believed that progress toward allowable claims was made.

Claim Rejections Under 35 USC 112

Claims 1, 3-6, 8, 10, 12, 13, 15, 17-34 and 36 stand rejected under 35 U.S.C. 112, second paragraph. The § 112, second paragraph rejection is traversed for at least the following reasons.

The Examiner states: “claims 1, 8, 17, 18, 22, 26 and 36 are indefinite and ambiguous because of the claim limitation of a space being elastic, porous but non-permeable space. The contradiction of porous and non-permeable is the first issue since an element is not capable of being both.” *Office Action, page 2, para. 3.* This position is traversed.

Porous material may be of two types. A first type of porous material has pores that are interconnected and open to the exterior, which allows air or liquid to pass from pore to pore to an exterior of the porous material. An example of porous material with interconnected, open pores is a sponge. A second type of porous material has pores that are not connected and are closed to the exterior, which prevents air or liquid to pass to the exterior of the porous material. An example of porous material with closed pores is insulating material that traps specialized gas within each of the closed pores to provide improved insulating properties. From the Office Action at page 2, it appears the Examiner is interpreting the claim limitation related to the pores

or spaces as meaning the pores are open to the exterior of the membrane. This interpretation is incorrect.

The specification of the present invention makes clear that the porous material is non-permeable and formed of closed pores: “the hollow spaces can also be formed by the pores of an elastic, porous, but overall non-permeable material, i.e. by means of a porous material whose pores are closed.” *U.S. Patent Application Publication 2004/0236274, para. 10* (the publication of the instant application). The figures and the specification have also been amended to include FIG. 1a and an associated description of the membrane 15 including pores 18 made of an elastic, porous, but overall non-permeable material 19. In order to expedite prosecution, the claims have been amended to clarify the compressible spaces, in claims 1, 8, 17-18, and 22 include “elastic, closed pore, non-permeable material [] within the at least one compressible space forming at least one hollow space in the membrane.” In addition, the figures and the specification have been amended to include FIG. 1b and an associated description of the membrane 15 including a non-porous portion 10 and a porous portion 30. Support for these modifications to the drawings, specification and claims can be found at paragraphs 10 and 30 of U.S. Patent Application Publication 2004/0236274.

In particular, for independent claims 1, 8, 17-18, and 22, “[s]paced from the central passage 16, a number of hollow spaces 17 are formed in the membrane 15. The hollow spaces 17 are formed by simple, linearly cylindrical passages which extend through the membrane 15 between the two facing areas of the membrane 15” (*Id. para. 30.*) , and “[i]nstead of by forming or shaping measures, or in combination with forming, the hollow spaces can also be formed by the pores of an elastic, porous, but overall non-permeable material, i.e. by means of a porous material whose pores are closed” (*Id., para 10.*). Accordingly, for claims 1, 8, 17-18, and 22, hollow spaces may be formed by the combination of cylindrical spaces and pores of an elastic, porous, but overall non-permeable material arranged therein to form at least one hollow space in the membrane. For independent claims 26 and 36, “[i]nstead of by forming or shaping measures, or in combination with forming, the hollow spaces can also be formed by the pores of an elastic, porous, but overall non-permeable material, i.e. by means of a porous material whose pores are closed. Such a porous material can also surround an elastic, non-porous material, and the passage would extend through the non-porous material.” Accordingly, for claims 26 and 36, the elastic membrane may include a porous portion surrounding the non-porous portion.

With respect to paragraphs 4 and 5 of page 2 in the Office Action, the language “not penetrable by the cannula” has been modified or removed in the claims.

Claim Rejections Under 35 U.S.C. 103(a)

Claims 1, 3-6, 8, 10, 12, 13, 15, 17-34 and 36 stand rejected under 35 U.S.C. 103(a) over Behnke et al. (US Patent 5,520,641) in view of Paul, Jr. (US Publication 2001/0041872). Claims 1, 3-6, 8, 10, 12, 13, 15, 17-34 and 36 stand rejected under 35 USC 103(a) over Ouchi (US Patent 6,210,377), and further in view of Paul, Jr. (US Publication 2001/0041872). The § 103(a) rejections are traversed for at least the following reasons.

As an initial matter, the Examiner’s attention is directed to the independent claims, each of which provides a compressible space or a hollow space, where elastic material presses against or compresses these spaces when a cannula is inserted through a passageway of the membrane. Compressible spaces in a membrane provides advantages because, for example, “[b]y forming at least one hollow space next to the passage, the passage can in principle exhibit any cross sectional shape.” *U.S. Patent Application Publication 2004/0236274, para. 11*. “[T]he membrane’s compressibility is achieved by forming at least one hollow space in the elastic material of the membrane next to the passage, into which space the membrane can be deformed when compressed.” *U.S. Patent Application Publication 2004/0236274, para. 10*. These advantages are neither disclosed nor suggested by the cited references. Further, as evidenced by the § 103 rejections, the Examiner does not identify anywhere in the cited references compressible spaces or hollow spaces as claimed in the amended independent claims.

1, 8, 17, 18 and 22 are not Obvious over Behnke et al. in view of Paul, Jr.

Behnke et al. in view of Paul, Jr. does not disclose or suggest a “compressible space” as claimed in amended claims 1, 8, 17, 18 and 22 in which an “elastic, closed pore, non-permeable material is within the at least one compressible space forming at least one hollow space in the membrane.”

In Behnke et al., the IV injection and sampling site is a septum with multiple openings, where it is “preferred that the openings 48 be located directly above the bore 46 and open into the same to facilitate insertion of the penetrators through the bore 46.” (*Behnke et al., col. 5, lines 9-11*). “The arrangement is such that [] a blunt cannula C is introduced through any one of

the openings 48 in the septum 26. . .” (*Behnke et al.*, col. 5, lines 12-13). Behnke et al. discloses openings extending through septum 26, any of which may be penetrated by cannula C. Accordingly, Behnke et al. does not disclose or suggest the claims 1, 8, 17, 18 and 22 membrane comprising a “compressible space,” as claimed.

In Paul, Jr., the medical fluid flow control valve includes a seal 26, where “[t]he seal 26 also possesses at least one . . . perforation 34 extending through it from the first face 30 to the second face 32.” *Paul, Jr.*, para. 47. As provided by the figures in Paul, Jr., perforation 34 may have a y-shape (Figs. 5A-C) or an oval-shape (6A-C), each of which may be penetrable by catheter 20. (*See Paul, Jr.*, page 5, paragraph 52). Although Paul, Jr. provides a perforation 34 penetrable by catheter 20, the perforation extends between the faces 30, 32 of seal 26, and Paul does not disclose the amended claims 1, 8, 17, 18 and 22 “compressible space.”

Moreover, modifying openings 48 in Behnke et al. to make them into hollow spaces of elastic, closed pore, non-permeable material would prevent a cannula from penetrating bore 46, which is contrary to the teachings of Behnke et al. in which “it is further preferred that the openings 48 be located directly above the bore 46 and open into the same to facilitate insertion of the penetrators through the bore 46.” (*Behnke et al.*, col. 5, lines 9-11).

Modifying the perforation 34 in Paul, Jr., to make hollow spaces of elastic, closed pore, non-permeable material would render seal 26 inoperable because no passage would be provided in seal 26 to allow catheter 20 to penetrate.

Accordingly, none of the cited references suggests openings or perforations in a membrane that may be modified to be configured as “compressible spaces,” and such a modification is contrary to the teachings in Behnke et al., and would render the seal 26 in Paul, Jr. inoperable for its intended purpose. Thus, the combination of Behnke et al. and Paul, Jr. does not disclose or suggest the recitations of amended independent claims 1, 8, 17, 18 and 22.

Claims 1, 8, 17, 18 and 22 are not Obvious over Ouchi in view of Paul, Jr.

Ouchi in view of Paul, Jr. does not disclose or suggest a “compressible space” as claimed in amended claims 1, 8, 17, 18 and 22 in which an “elastic, closed pore, non-permeable material is within the at least one compressible space forming at least one hollow space in the membrane.”

In Ouchi, the treatment accessory for an endoscope includes a forceps tap 2600 with packing 2721 having configurations including a slit 2723 (Fig. 83), double slits 2725, 2726 (Fig. 84), a combination of two vertical slits 2725, 2726 and a horizontal slit 2723 (Fig. 85), a combination of a vertical slit 2725 and a through hole 2727 (Fig. 86), and a combination of two through holes 2727, 2728 (Fig. 87). Each of the slit/hole configurations disclosed in Ouchi extend through the ends of forceps tap 2600 to allow treatment accessories to penetrate the tap, and Ouchi does not disclose a membrane comprising a “compressible space” as claimed.

As discussed above, Paul, Jr. does not disclose or suggest a membrane comprising a “compressible space,” as claimed, and modifying perforation 34 to make it non-permeable would render it inoperable for its intended purpose because no passage would be provided in seal 26 to allow catheter 20 to penetrate.

Further, nothing in Ouchi suggests that slits or through holes may be modified to make them into a “hollow spaces of elastic, closed pore, non-permeable material.” Accordingly, neither Ouchi nor Paul, Jr. disclose or suggest the recitations of amended independent claims 1, 8, 17, 18 and 22.

Claims 26 and 36 are not Obvious over Behnke et al. in view of Paul, Jr.

Behnke et al. in view of Paul, Jr. does not disclose or suggest a “membrane” having “a porous portion surrounding the non-porous portion,” where the porous portion has “a plurality of spaces that are elastic, closed pore, and non-permeable spaces” as provided in amended claims 26 and 36.

For Behnke et al. and Paul, Jr., each of openings 48 and perforation 34, respectively, are penetrable by cannula C/20, and neither reference suggests openings 48 or perforation 34 may be modified so that they include a number of spaces that are elastic, closed pore, and non-permeable spaces in elastic material.

Modifying openings 48 in Behnke et al. to make them spaces that are elastic, closed pore, and non-permeable spaces in elastic material, would make the openings 48 not penetrable by a cannula or at least would not facilitate insertion of the penetrators, which is contrary to the teachings of Behnke et al., in which “it is further preferred that the openings 48 be located

directly above the bore 46 and open into the same to facilitate insertion of the penetrators through the bore 46.” *Behnke et al.*, col. 5, lines 9-11.

Further, modifying the perforation 34 in Paul, Jr. to make it not penetrable by a catheter would render seal 26 inoperable because no passage would be provided in seal 26 to allow catheter 20 to penetrate.

Accordingly, providing a membrane comprising “a porous portion surrounding the non-porous portion,” where the porous portion has “a plurality of spaces that are elastic, closed pore, and non-permeable spaces,” as claimed in claims 26 and 36, is not suggested because such a modification would be contrary to the teachings in Behnke et al., and modifying the seal 26 in Paul, Jr. would render it inoperable for its intended purpose. Accordingly, the combination of Behnke et al. and Paul, Jr. does not disclose or suggest the recitations of claims 26 and 36.

Claims 26 and 36 are not Obvious over Ouchi in view of Paul, Jr.

Ouchi in view of Paul, Jr. does not disclose or suggest “a porous portion surrounding the non-porous portion,” where the porous portion has “a plurality of spaces that are elastic, closed pore, and non-permeable spaces” as provided in amended claims 26 and 36.

For Ouchi and Paul, Jr., each of slits, through holes and perforations are penetrable by a treatment accessory/cannula. There is no indication in either Ouchi or Paul, Jr. that such cannula-accessible openings may be modified to make them non-cannula accessible. Accordingly, Ouchi and Paul, Jr., viewed alone or in combination, do not disclose or suggest providing the “porous portion” of the membrane as claimed in amended claims 26 and 36.

The Behnke or Ouchi in view of Paul, Jr. do not disclose or suggest the recitations of at least the independent claims, and reconsideration and withdrawal of the § 103 rejections are requested.

Dependent Claims

Dependent claims 3-6, 10, 12, 13, 15, 19-21, 23-25 and 27-32 depend directly or indirectly from their respective independent claims 1, 8, 18, 22 and 26 and are patentable for at least the reasons set forth above, and further in view of their additional recitations.

For at least the preceding reasons, reconsideration and withdrawal of the § 103(a) rejections over Behnke et al., Ouchi and Paul, Jr. are requested.

Conclusion

This response is being submitted on or before September 2, 2008, with the required fee of \$120 for a one-month extension of time, making this a timely response. It is believe that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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Date:

September 2, 2008

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